

JAN 19 2006

K053056

## 510(k) Summary

**Company** Ethicon Endo-Surgery, Inc.  
4545 Creek Road  
Cincinnati, OH 45242

**Contact** Elizabeth Miller  
Regulatory Affairs Associate II  
Telephone: (513) 337-7146  
Fax: (513) 337-1444  
Email: lmiller12@eesus.jnj.com

**Date Prepared** October 28, 2005

**Device Name** Trade Name: Harmonic Scalpel Blades and Shears  
Common or Usual Name: Instrument, Ultrasonic Surgical  
Classification Name: Electrosurgical Cutting and Coagulation Device  
[21 CFR 878.4400 (LFL)]

**Predicate Device** UltraCision Harmonic Scalpel Blades and Shears

**Device Description** The Harmonic Scalpel Blades and Shears are ultrasonic surgical instruments for the cutting and coagulation of soft tissue incisions when bleeding control and minimal thermal injury are desired. The device system has three essential parts: the generator/footswitch, the hand piece and the instruments, which are available in various lengths shapes and types. The selection of the appropriate instrument is a matter of surgeon preference.

**Indications for Use** The Harmonic Scalpel Shears Instruments are indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired. The instruments can be used as an adjunct to or substitute for electrosurgery, lasers, and steel scalpels in general, *plastic*, pediatric, gynecologic, urologic and other open and endoscopic procedures.

The Harmonic Scalpel 5 mm Instruments with Protective Sleeve is indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired. The instruments can be used as an adjunct to or substitute for electrosurgery, lasers, and steel scalpels in general, *plastic*, gynecologic, ENT (Ears, Nose, Throat), including tissues of the soft palate, oral structures, and oropharyngeal airway, and thoracic surgery, including mobilization of the Internal Mammary Artery (IMA).

The Harmonic Scalpel 10cm Sharp Curved Blade instruments are indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired. The instrument can be used as an adjunct to or substitute for electrosurgery, lasers, and steel scalpels in general, *plastic*, gynecologic, and thoracic surgery.

The Harmonic Scalpel 10cm Curved Blade Instrument is intended to cut and coagulate soft tissue. It is to be used when bleeding control and minimal thermal injury are desired. The instrument can be used as an adjunct to or substitute for electrosurgery, lasers, and steel scalpels in general, *plastic*, gynecologic, ENT (Ears, Nose, Throat) and thoracic surgery, including mobilization of the Internal Mammary Artery (IMA).

The Harmonic Scalpel 5 mm Instruments are indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired. The instruments can be used as an adjunct to or substitute for electrosurgery, lasers, and steel scalpels in general, *plastic*, gynecologic, and thoracic surgery, including mobilization of the Internal Mammary Artery (IMA).

**Technological Characteristics** The Harmonic Scalpel Blades and Shears technological characteristics are the same as the predicate device. No changes (materials construction, specifications, manufacturing or sterilization processes) to the currently marketed device. The device differs only in the indications.

**Performance Data** A clinical literature search was performed to show the use of the devices in plastic surgery.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

JAN 19 2006

Ms. Elizabeth Miller  
Regulatory Affairs Associate  
Ethicon Endo-Surgery, Inc.  
4545 Creek Road  
Cincinnati, Ohio 45242

Re: K053056

Trade/Device Name: Harmonic Scalpel Blades and Shears  
Regulation Number: 21 CFR 878.4400  
Regulation Name: Electrosurgical cutting and coagulation device and accessories  
Regulatory Class: II  
Product Code: LFL  
Dated: October 28, 2005  
Received: October 31, 2005

Dear Ms. Miller:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

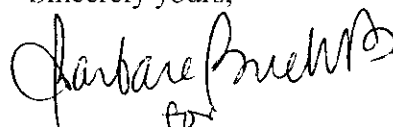
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson", with a stylized flourish at the end.

Mark N. Melkerson  
Acting Director  
Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K 053056

Device Name: **Harmonic Scalpel Blades and Shears**

### Indications for Use:

The Harmonic Scalpel Shears Instruments are indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired. The instruments can be used as an adjunct to or substitute for electrosurgery, lasers, and steel scalpels in general, *plastic*, pediatric, gynecologic, urologic and other open and endoscopic procedures.

The Harmonic Scalpel 5 mm Instruments with Protective Sleeve is indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired. The instruments can be used as an adjunct to or substitute for electrosurgery, lasers, and steel scalpels in general, *plastic*, gynecologic, ENT (Ears, Nose, Throat), including tissues of the soft palate, oral structures, and oropharyngeal airway, and thoracic surgery, including mobilization of the Internal Mammary Artery (IMA).

The Harmonic Scalpel 10cm Sharp Curved Blade instruments are indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired. The instrument can be used as an adjunct to or substitute for electrosurgery, lasers, and steel scalpels in general, *plastic*, gynecologic, and thoracic surgery.

The Harmonic Scalpel 10cm Curved Blade Instrument is intended to cut and coagulate soft tissue. It is to be used when bleeding control and minimal thermal injury are desired. The instrument can be used as an adjunct to or substitute for electrosurgery, lasers, and steel scalpels in general, *plastic*, gynecologic, ENT (Ears, Nose, Throat) and thoracic surgery, including mobilization of the Internal Mammary Artery (IMA).

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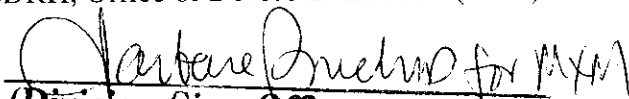
Prescription Use   X    
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
(Division Sign-Off)

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**Division of General, Restorative,  
and Neurological Devices**

(Posted November 13, 2003)

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